

REMARKS

The undersigned attorney would like to thank Examiner Bhat for participating in a telephone interview regarding the outstanding rejection. Although the discussion of the cited reference and the claimed invention was believed to be helpful, no agreement was reached. If upon review of the remarks below the Examiner believes additional discussion would further the prosecution of the present case, the Examiner is invited to call the undersigned attorney.

Claims 1-3, 5, 8-10, 14, and 19-24 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,629,060. Applicant respectfully disagrees with the Examiner's characterization of the reference and the rejection based thereon.

The '060 Patent provides a quality control method and a device that utilizes an information control terminal connected to analyzers via a network (col. 3, lines 19-41). The analyzers perform assays of quality control substances and transmit the assay data to the information terminal. Communication between the information terminal and the analyzers is performed through a dedicated NTT line, a network, the internet, or the like. (Col. 3, lines 52-56; see also Col. 4, lines 4-7). The information terminal tallies the sample data and outputs the tallied data back to the analyzer, where the analyzer operator makes a quality control check on the analyzer.

The '060 Patent therefore describes a method and an apparatus that includes an information terminal remotely located from one or more analyzers. Quality control procedures require an initial data transfer from the analyzer(s) to the information terminal, and a subsequent data transfer from the information terminal to the analyzer. Consequently, an analyzer operating in a location where it cannot be connected to the information terminal via a network, internet, or the like cannot be subject to quality control procedures.

Claims 1, 19, and 24 of the present application, in contrast to the cited reference, recite a method for providing quality control in an analytical instrument that comprises the steps of, *inter alia*, analyzing one or more quality control specimens using the analytical instrument and thereby creating instrument analysis data, and a subsequent step of performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data. Consequently, the analysis and evaluation are both performed within the same analytical instrument. This characteristic provides significant advantages. Point-of-care devices are typically used in a variety of different environments, many of which do not allow for connection to another apparatus or a central database. The present invention

allows for quality control procedures without connection to another apparatus or a central database. The location of the point-of-care device is, therefore, not an issue. Another advantage is the ease of administering the quality control procedure. Under the present invention, there is no connection to another apparatus or a central database. Consequently, the requirement to make the connection and the possibility for error in such connection is eliminated.

Claims 2, 3, 5, 8-10, and 14 depend from claim 1. For the reasons provided above relative to claim 1, applicants respectfully submit that claims 2, 3, 5, 8-10, and 14 are patentable in view of the cited references. Applicants, therefore, request these claims be allowed and passed onto issuance.

Independent claim 20 and dependent claims 21-23 recite a quality control system for analytical instruments that comprises "an analytical instrument, having an analyzer for analyzing the one or more quality control specimens, and thereby create instrument analysis data that includes one or more sensed characteristic values" and "means for performing an evaluation of the analytical instrument within the analytical instrument using the instrument analysis data and the predetermined characteristic values to determine a functional status of the analytical instrument". For the reasons provided above relative to claims 1 and 19, applicants respectfully submit that claims 20-23 are patentable in view of the cited references. Applicants, therefore, request claims 20-23 be allowed and passed onto issuance.

As applicants have traversed each rejection and objection raised by the Examiner, it is respectfully requested that the Examiner withdraw the stated rejections and objections, allow claims 1-3, 5, 8-10, 14, and 19-24, and pass the present application on to issuance. No fee is believed due with the present response. In the event a fee is due, however, please charge our Deposit Order Account No. 50-3381.

Respectfully submitted,

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